

JRC SCIENTIFIC AND POLICY REPORTS

Annual Activity Report 2012

European Union Reference Laboratory for Food Contact Materials



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2013



EUR 26187 EN

European Commission
Joint Research Centre
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JRC84219

EUR 26187 EN

ISBN 978-92-79-33268-5 (pdf)

ISSN 1831-9424 (online)

doi:10.2788/29363

Luxembourg: Publications Office of the European Union, 2013

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Printed in Italy



EC-JRC-IHCP, CAT Unit
action programme 15014

2012

EURL Food Contact Materials
No SANCO/2011/FOOD SAFETY070-Food Contact Materials

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Executive summary

In 2012, three interlaboratory comparisons (ILC) were completed. The ILCs were

- 1) The evaluation of a method for migration into a dry material (Tenax) that officially simulates all dry foods,
- 2) A determination of melamine and of formaldehyde in 3% acetic acid migration solutions, and
- 3) A determination of primary aromatic amines in 3% acetic acid migration solutions.

The deliverables also included the collation by the EURL of food contact substances from the positive list and methodology for their determination in plastics, food simulants or foodstuffs, work to establish methodology for mineral hydrocarbons, and training activities carried out by the EURL.

Legal functions and duties:

Regulation (EC) No. 882/2004 (OJ L 165 vol 47 of 30.04.2004, page 1-141) of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OFFC), includes provisions for the management of European Union Reference Laboratories (EURLs) in the whole sector, including (Article 32) on their responsibilities (mission/duties).

Article 32 - EURLs (referred to in Annex VII) shall be responsible for:

- (a) *Providing national reference laboratories (NRLs) with details of analytical methods, including reference methods;*
- (b) *coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organizing comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;*
- (c) *Coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;*
- (d) *Conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;*
- (e) *Providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;*

Note: National Reference Laboratories: NRLs

Objectives for the period January –December 2012

The objectives were based on the duties listed in OFFC organized as activities areas.
The classification mirrors the areas listed in Reg. EC 882/2004:

Core Area 1: Methodologies for sampling and analysis

1a – methods of analysis protocols (Art 32 1(a))

- 1a-1 Guidelines on sampling, test conditions with an emphasis on articles to be placed in contact with food for home use – 2nd edition in support to new Regulation 10/2011
- 1a-2 Continuation of repository of methods of analysis from EFSA /petitioner's sources
- 1a-3 Support to Official Controls with calibrants
- 1a-4 Follow up of the interlaboratory comparison on Tenax

1b – Organisation of comparative testing (Art 32 1(b))

- 1b1 Interlaboratory comparison No1: Formaldehyde and melamine from migration solution
- 1b2 Interlaboratory comparison No2: Primary aromatic amines from migration solution

1c - Emerging issues and methods (art. 32 1(c))

1d – Training (Art 32 1 d)

1e- Technical / scientific support to Commission in case of disputes

Core Area 2: General tasks

2.1 Operational procedures

- 2.1.1 Compilation of annual report and cost estimates
- 2.1.2 Documentation services and communication
- 2.1.3 Ad-hoc questions or exchange of information with NRLs
- 2.1.4 Technical and scientific support to the Commission (EURL context)
- 2.1.6 Organisation of plenary and workshops

2.2 Quality assurance and control

Activity area 1a: methodologies for sampling and analysis

1a-1- Second edition of Guidelines on sampling, test conditions for articles to be placed in contact with food for home use

As a follow up of the 1st edition published in 2009, a 2nd edition to adapt the Guidelines on kitchenware to Regulation (EU) No 10/2011 is needed in line with development of a more general migration testing technical guidance for the Regulation (EU) No 10/2011 itself. The guidelines specifically target kitchenware items and aim to address sampling, treatment of specimen, exposure testing (e.g. time/temperature, simulant etc), interpretation of results. The priority tasks for revisions are: 1) the fit to the new regulation (test conditions and choice of simulants), 2) the removal of some extraneous items 3) indications for bakeware.

A technical guidance specific to issues on migration testing is currently being developed by JRC for DG SANCO with a small task force of experts. Once the guidelines on migration testing in support of Regulation 10/2011 will be completed they will be available for endorsement by all NRLs. Consequently the update of the guidelines of kitchenware needs to await the development of these overarching Guidelines under Reg. 10/2011.

Therefore this item of the work programme is postponed to mid 2013 to adhere to the fit for purpose progression of the overall technical guidelines. This work will be carried out in 2013 following completion of the Technical guidelines in support of Regulation (EU) No 10/2011.

1a-2 Provision of methods of analysis protocols

Methodologies for the analysis of plastic food contact materials monomers and additives have been collected from EFSA petitions and former SCF dossiers where the case. For each method, the technical descriptions of applicant's methods are made anonymous and transposed into a CEN format.

The database listing of the methods is available (on the Circabc platform EURL-NRL-FCM) for NRLs and the full method descriptions are sent upon request. No new methods were received in 2012.

In 2013 this database of methods will be merged with the database for substances into a one stop portal that will be made publicly available on the EURL website.

1 a-3- Support to official controls with calibrants

Work was carried out to establish sources of analytical standards required as calibrants for the enforcement of Regulation (EU) No 10/2011.

Several are not commercially available and are not included in the EURL standards collection (combining the monomers, additives collections and chemicals received supporting recent EFSA petitions). Many of the substances in the EURL collection are dating from 1990s and are not representative of the current chemical market situation. To replace each would be a costly exercise considering that the EURL only receives ~ 10 requests for substances each year.

Therefore the EURL undertook a systematic study evaluate the situation for all 954 substances in the FCM DG SANCO positive list in January 2012.

Traceability to a commercial analytical supplier was achieved for 738 substances;

216 substances were not found commercially. Of those, 122 had no CAS number which made the search for suppliers more difficult. 94 substances were not found although they had a CAS number.

An update of the database collection and sources was uploaded onto the EURL-NRL-FCM platform Circabc on 22.05.2012. It was redeveloped in the form of an excel sheet now based on the model from the DG SANCO databank (https://webgate.ec.europa.eu/sanco_foods/main/?event=substances.search&substance.s.pagination=1). The EURL numbering system was changed to match that of DG SANCO in order to facilitate cross referencing. The worksheet contains the substances of the positive list and where they can be found (supplier and website).

The next steps are to continue the search via other suppliers and for 2013 to start a phase 2 establishing a collaboration with the industrial association CEFIC on current suppliers in the EU for the substances.

The EURL also prepared and sent upon request standard calibrants to NRLs and other stakeholders for use for research or enforcement purposes. The requests have all been met timely.

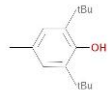
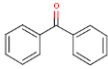
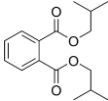
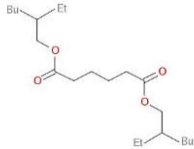
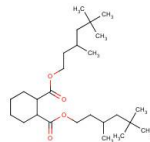
1a-4- Completion /follow up of the method validation for simulant E

Regulation (EU) No 10/2011 establishes (poly (2,6-diphenyl phenylene oxide, PPPO)) as food simulant E for testing specific migration from plastics into dry foodstuffs. Although research data have been available, there was to date no precision or validation data on the ability of a method both for the testing of specific migration and for the subsequent quantification of representative substances from PPPO.

Previous research done in 2010-2011 by the EURL-FCM focused on the development and the optimisation of a standard operation procedure for using the new simulant E for testing specific migration into dry foodstuffs. A preliminary part of the research focused on potential substances that responded to criteria of being able to migrate into PPPO from a spiked film, able to be homogeneously spiked into PPPO and into a plastic film, be stable in the film and in PPPO, and be representative a of a range of substances that are common food contact additives.

The outcome of the preliminary research led to the selection of substances (table 1) chosen as models for the subsequent interlaboratory comparison (ILC) exercise due to their migration properties and stability characteristics in a plastic film and in PPPO.

Table 2. Substances selected for the validation for simulant E.

Name (Abbreviation)	CAS No.	Structure	MW
Butylhydroxytoluene, 2,6-di-tert-butyl-p-cresol (BHT) IUPAC: 2,6-bis(1,1-dimethylethyl)-4-methylphenol	128-37-0		220.35
Benzophenone (BP) IUPAC: Methanone, diphenyl	119-61-9		182.22
Diisobutylphthalate (DiBP) IUPAC: Bis(2-methylpropyl)benzene-1,2-dicarboxylate	84-69-5		278.35
Diethyladipate (DEHA) IUPAC: Bis(2-ethylhexyl)adipate	103-23-1		370.64
1,2-cyclohexanedicarboxylic acid, diisononyl (DINCH) IUPAC: 1,2-bis(3,5,5-trimethylhexyl) cyclohexane-1,2-dicarboxylate	166412-78-8		424.66

An efficient analytical method was developed for the quantification of the range of substances investigated from PPPO including extraction of the PPPO followed by GC-MS analysis. A method for fortifying PPPO and polyethylene film (LDPE) with a range of model substances (surrogates) was also developed. An experimental design was also developed for the migration tests using smaller migration test cells (using 1g Tenax per sample) than the larger conventional ones (using ca 4g Tenax per sample) to provide a more cost efficient design¹.

The subsequent ILC was conducted at EU level. The general aim of the ILC was to establish precision criteria of the harmonised method for the extraction and quantification of the models substances from PPPO and also for the migration test from a fortified plastic film into PPPO followed by their subsequent quantification. The ILC also evaluated the laboratory performance.

The EURL prepared and proposed a Standard Operating Procedure (SOP) describing the exposure of a plastic material or article (intended for use with dry foods) to PPPO and the subsequent extraction of the PPPO and analysis of the extract. The exercise foresaw: 1) one part using a spiked PPPO for which the ILC focused on extraction from PPPO itself and quantification of surrogate substances 2) another part using a film specifically contaminated with a selection of substances for which the ILC consisted of the exposure of a film to PPPO and subsequent extraction and quantification. This allowed to obtain data on precision and laboratory performance for both migration and quantification.

¹ Considering the price of Tenax is 200€/gram

The test materials used in this exercise were spiked PPPO samples prepared by the EURL-FCM with three levels of model substances and a spiked LDPE film to perform the migration part of the exercise. The homogeneity and stability studies were performed by the EURL-FCM.

There were 17 volunteer laboratories participating from 15 countries to whom samples were dispatched and 16 of which submitted results. From the EURL-NRL network 14 laboratories out of 15 reported results. There were 2 guest laboratories from Germany that provided results as well. Since the aim of the ILC was primarily to obtain precision criteria there was a communication to the participants to use the harmonised protocol developed. Participants were invited to report four replicates measurements under repeatability conditions. This was done by most of the participants. The results of analyses were received and statistically interpreted. The assigned values were obtained as a consensus values after applying the robust statistics to the results obtained from the participants. Laboratory results were also rated with z-scores in accordance with ISO 13528.

The results showed that the validation ILC was successful with more than 8 valid results even taking into account the complexity of the exercise. The results showed that the method performance could be estimated to 7-9% repeatability standard deviation (rsd) for most substances (regardless of concentration), with 12% rsd for the high level of BHT and for DiBP at very low levels. The reproducibility results for the 16 EU laboratories were summarised as performance indicators of the method for the quantification from PPPO (for the 3 levels of concentrations of the 5 substances) as well as from migration experiments from the fortified plastic at 60C for 10 days and subsequent quantification.

Reproducibility S.D. (%) calculated by ISO 5725-5 for the different exercises (LL: legislative limit, i.e. specific migration limit, SML) are summarised below.

Substance	LL value mg/kg	R sd % at 1/10 * LL	R sd % at the LL	R sd % At 2 * LL	R sd % From FILM
BHT	2	45%	28%	19%	41%
BP	0.6	(/2) 21%	20%	17%	22%
DiBP	--	40%	30%	26%	25%
DEHA	18	29%	21%	16%	35%
DINCH	60	24%	21%	16%	16%

Considering the lack of the data previously available in the literature, this interlaboratory comparison exercise provided a method description which was tested and evaluated, and most importantly the first successful attempt to derive precision data at EU level for a test targeting specific migration. It also represented a challenging scenario and was very extensive with 3 levels of concentrations and 1 film, 5 substances, 4 replicates and results from 16 laboratories, i.e. 1360 data points. This exercise consequently provided a great breadth of valuable detailed and traceable precision data. The exercise has demonstrated that the validation of a method is possible both for migration and for quantification. As another added value, the EURL

together with its network of NRLs agreed on a follow up strategy, and therefore the WP 2013 will contain a work item using Tenax.

The follow-up proficiency test exercise for 2013 will be expanded to include polar analytes as well as undisclosed substances to assess a laboratories capability to detect, to identify and to measure unknowns.

Report:

Development of a harmonised method for specific migration into the new simulant for dry foods established in Regulation 10/2011: Establishment of precision criteria from an EU interlaboratory comparison organized by the EURL- Food Contact Materials for the quantification from and migration into poly(2,6-diphenyl phenylene oxide), BELDI Giorgia, JAKUBOWSKA Natalia, PEYCHES BACH Aurelie and SIMONEAU Catherine, EUR 25680 EN (2012), ISSN: 1831-9424, ISBN: 978-92-79-28078-8, doi: 10.2788/76804.

The full report can be found at:

<http://publications.jrc.ec.europa.eu/repository/handle/11111111/27288>

Activity area 1 b - Organisation of comparative testing

The Institute for Health and Consumer Protection (IHCP) of the European Commission's Directorate-General Joint Research Centre hosts the EU Reference Laboratory for Food Contact Materials (EURL-FCM). One of its core tasks is to organise interlaboratory comparisons (ILCs) among appointed National Reference Laboratories (NRLs).

1 b1- Interlaboratory comparison exercise 2012_001: Formaldehyde and melamine in 3% acetic acid from a migration solution of kitchen utensils

The second ILC focused on the quantification of formaldehyde and melamine in migration solutions of 3% acetic acid from food contact materials. The test material used for preparation of the migration solutions were melamine kitchenware (spoons). The migration was done in 3% acetic acid (w/v) which is the simulant for acidic foods and represents the worst case scenario for melamine plastics. The EURL prepared and distributed three concentration levels of migration solutions and three spoon samples (only for NRLs).

The exercise aimed at proficiency testing. The purpose of the exercise was 3 fold:

- Demonstration of the continued capacity of NRLs and guests to perform adequately the measurement of formaldehyde from a migration solution in the context of support to Regulation (EU) No 284/2011 for melamine kitchenware.
- Demonstration and provision to the accreditation body of the third line control for the accreditation of NRLs and guests for the method for formaldehyde.

- Demonstration of the capacity of NRLs and guests to execute the measurement (quantification) of melamine from melaware at the new limit foreseen under an upcoming amendment of Regulation (EU) 10/2011.

The general aim of the exercise was to assess the performance of the official control laboratories (proficiency test) and was mandatory for NRLs and open to guest OCLs for the test solutions. As a proficiency testing (PT), participants were free to use any analytical method of their choice.

The test material used for preparation of the migration solutions were melamine kitchenware (spoons) containing formaldehyde and melamine. The EURL prepared and distributed three concentration levels of migration solutions in 3% acetic acid and three spoon samples (only for NRLs). The migrate was diluted with different volumes of 3% acetic acid to generate the 3 test solutions F&M01 and F&M02 and without dilution to generate test solution F&M03. Spoons had been purchased and were available to be tested on a voluntary basis since they did not pass the homogeneity test.

The homogeneity and stability studies were performed by the EURL-FCM laboratory. The stability tests were performed according to ISO Guide 35:2006 at 3 levels and 3 temperatures.

Participants were invited to report 4 results for each concentration level and 2 results for each spoon. Laboratory results were processed using several algorithms: ISO 13528, Harmonized protocol, DIN 38402 A45 (Q-Hampel) and ISO GUIDE 35:2006. The assigned values were obtained after applying the robust statistics to the results of the participants. Standard deviations for proficiency assessment (also called target standard deviations) were set based on Horwitz equation.

There were 70 participants to whom samples were dispatched (EURL, 27 NRLs + 42 national control laboratories (OCLs) from Belgium, France, Germany, Italy, Poland, Slovenia, Spain and United Kingdom) and 66 of which submitted results. Four laboratories did not submit results, 35 laboratories submitted results for formaldehyde and melamine, 27 submitted only results from formaldehyde and 4 laboratories only melamine results.

As a conclusion of the ILC exercise on the quantification of formaldehyde and melamine in the migration solutions of kitchenware in 3% acetic acid, this ILC showed that:

The level of participation was 94%, of which 88.5% for formaldehyde, 56% for melamine and 50% for both substances under test. As this ILC targeted the correct implementation of Regulation 284/2011 on China and Hong Kong imports which requires the analysis of 10% of the consignments, all reporting laboratories were expected to report at least results for formaldehyde.

The level of success in the exercise was of 80% of correctly estimated results for formaldehyde and 89% for melamine (for all three concentration levels) when considering all 66 laboratories comprising of NRLs and OCLs. With regards to the performance of NRLs only, 79 % of all reported results were correctly estimated for formaldehyde, and 88% for melamine.

Therefore for this exercise and the enforcement of the physical tests for consignment of imports under Regulation 284/2011, the OCLs and NRLs performance was the same and can be considered as one unique population in terms of reliability of results.

Therefore they are equally qualified towards performing duties stemming from the 10% physical checks to be done under Regulation 284/2011.

The results and z-scores for NRLs were further investigated specifically on formaldehyde for the 62 laboratories who submitted results. The results for F&M01 and F&M02 had 7 of the 62 laboratories (ca. 11%) returning questionable or unsatisfactory results. For the third solution, F&M03, 23 of the 62 laboratories (ca. 37%) returned questionable or unsatisfactory (i.e. z-score higher than 2). The third sample required dilution step before analysis, which could have caused the highest robust reproducibility standard deviation value, so possible reasons were investigated.

The EURL-FCM will therefore follow up with a questionnaire in order to identify the potential processes that led to the questionable or unsatisfactory performance (including how and when diluted, what was the measured concentration and what was the calibration range). This will constitute the first measure (root cause analysis) as prescribed by Eurachem for underperformance. The second measure will be the production of a new blind solution that will be sent to underperforming NRLs and give the opportunity to improve performance.

For melamine, F&M01, F&M02 and F&M03 88% of the laboratories reported satisfactory results.

With regards to the migration experiments (i.e. from spoons), nineteen volunteer laboratories from the NRL-FCM network participated in the migration exercise by analysing melamine kitchenware (spoons). All the laboratories submitted their results. An optional part of this exercise was to determine the contact area of the utensils. Only a small number of laboratories returned results however the distribution of results was wide. The data highlighted that the release of formaldehyde does not follow a diffusion-led migration as the results between 1st, 2nd and 3rd migration did not decrease steadily and remained somewhat unpredictable. The results confirmed a great variability between kitchen items for the high migrating non-compliant articles, indicating a lack of good manufacturing practices in their production.

Report:

Report of the interlaboratory comparison organised by the European Reference Laboratory for Food Contact Materials: ILC01 2012- Formaldehyde and Melamine in 3% acetic acid migration solution, BELDI Giorgia, JAKUBOWSKA Natalia, YAVUZ Oguzhan and SIMONEAU Catherine, EUR 25686-EN ISSN: ISSN 1831-9424, ISBN: 978-92-79-28085-6, doi:10.2788/77358

The full report can be found at:

<http://publications.jrc.ec.europa.eu/repository/handle/111111111/27246>

1 b2- Interlaboratory comparison exercise 2012_002: Primary aromatic amines (PAAs) in 3% acetic acid from a migration solution

The other ILC focused on the quantification of primary aromatic amines (PAAs) in 3% acetic acid exposed to nylon utensils.

The exercise aimed at proficiency testing. The purpose of the exercise was 2 fold:


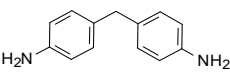

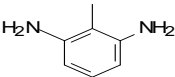
- Demonstration of the continued capacity of NRLs and guests to perform adequately the measurement of PAAs from a migration solution in the context of support to Regulation (EU) No 284/2011 for polyamide kitchenware.
- Demonstration and provision to the accreditation body of the third line control for the accreditation of NRLs and guest for a method of PAAs.

This ILC targeted the correct implementation of Regulation 284/2011 on China and Hong Kong imports of kitchenware which requires the analysis of 10% of the consignments. All NRLs were expected to take part in the exercise. The general aim of the exercise was proficiency testing, the participants were - in principle - free to use any analytical method of their choice. However, in view of the support to Regulation 284/2011, the methods of choice focused on the procedures described in the Annex of the JRC technical guidelines (EUR 24815 EN 2011) of Regulation 284/2011.

The test material used for preparation of the migration solutions were polyamide kitchenware containing PAAs kindly prepared by the NRL-UK.

Aniline, 2,4 TDA, 2,6 TDA and 4,4 MDA were selected to be the migrants (table 2). The selection was based on questionnaires sent to all NRLs on substances 1) most commonly found 2) most used as target monitoring substances in the official controls.

Table 2. Primary Aromatic Amines quantified in the ILC02 2012 PAAs.

Name (Abbreviation)	CAS No.	Structure	MW
Aniline (ANL)	62-53-3		93.1
4,4'-Methylenedianiline (4,4'-MDA)	101-77-9		198.3
2,4-Toluenediamine (2,4-TDA)	95-80-7		122.1
2,6-Toluenediamine (2,6-TDA)	823-40-5		122.1

Two concentration levels of migration solutions were distributed to the NRLs.

The homogeneity and stability studies were performed by the NRL UK laboratory and statistically elaborated from the EURL-FCM. The stability test was performed according to ISO Guide 35:2006 at 3 temperatures.

Participants were invited to report 4 results for each concentration level. Laboratory results were processed using several algorithms: ISO 13528, Harmonized protocol, DIN 38402 A45 (Q-Hampel). The assigned values were obtained after applying the robust statistics to the results of the participants. Standard deviations for proficiency assessment (also called target standard deviations) were set based on Horwitz equation.

There were 29 participants to whom samples were dispatched (EURL, 27 NRLs + 1 guest from Belgium) and 27 of which submitted results. 24 laboratories submitted

results obtained using the chromatographic methods stipulated in the technical guidelines towards the implementation of the Regulation EU 284/2011 on imports. 3 laboratories reported their results as equivalent of aniline/kg using a spectrophotometric method, i.e. with a method which was not fit for the purpose of the exercise, so those results could not be taken into consideration. The level of participation in this ILC was 93% overall.

The results of the proficiency were as follows:

For the first concentration level PAAs, cocktail 1:

- ANL : 87.5% of the results were satisfactory; 8.3% were questionable and 4.2% were unsatisfactory;
- 4,4-MDA: 91.3% of the results were satisfactory; 8.7% were questionable and none was unsatisfactory;
- 2,4-TDA: 90.5% of the results were satisfactory; 9.5% were questionable and none was unsatisfactory.

For the second concentration level PAAs, cocktail 2:

- ANL : 100 % of the results were satisfactory;
- 4,4-MDA: 91.3 % of the results were satisfactory; none was questionable and 8.7 % were unsatisfactory;
- 2,4-TDA: 95.2 % of the results were satisfactory; 4.8 % were questionable and none was unsatisfactory;
- 2,6-TDA: 88.2 % of the results were satisfactory; 5.9 % were questionable and 5.9 % were unsatisfactory.

This exercise showed that there were no particular issues regarding the analysis (identification and quantification) of the most common PAAs and for the effective enforcement of the Regulation EU 284/2011 at least for the 24 laboratories using the suggested chromatographic method.

Report:

Report of the interlaboratory comparison organised by the European Reference Laboratory for Food Contact Materials: ILC02 2012- Primary Aromatic Amines in 3% acetic acid migration solution, BELDI Giorgia, JAKUBOWSKA Natalia, BRADLEY Emma, SIMONEAU Catherine, EUR 25685-EN (2012), ISSN: 1831-9424, ISBN: 978-92-79-28084-9, doi: 10.2788/77260.

The full report can be found at:

<http://publications.jrc.ec.europa.eu/repository/handle/111111111/27243>

Activity Area 1c - Emerging issues and methods

A conference forum in September 2011 organised by NRL-DE highlighted the methodology, toxicity and various methods in the context of occurrence of contamination of mineral oils from cardboard. A 'method development kit' including

standard solutions of n-alkanes, standard solutions of typical mineral oils, extracts of carton board and mineral oil spiked food (rice) was in development at NRL-DE.

In this context, the WP 2012 had a work item of voluntary collaboration in this emerging area towards the development and improvement of methods for the analysis of mineral oils from paper and board. The objective was first and foremost to exchange information during the plenaries.

Following the purchase of LC-GC-FID instrumentation the EURL used the NRL-DE method development kit to set up the method in-house. The intent was to check the methodology in-house on this instrument which was both from a different brand and had a different type of LC-GC interface to provide an on-line method.

This was successfully achieved and the data compared well to that of NRL-CH and NRL-DE. The only issues reported were the loss of some of the higher boiling MOAH² during the HPLC separation, loss of some of the lower boiling MOSH³ during the evaporation step and difficulties with consistent integration of the MOSH and MOAH 'humps'.

The NRL-DE and NRL-CH have already set up the method in their laboratories. None of the other NRLs had set the methodology up in their laboratories. The EURL is thus not planning to carry out a campaign on mineral hydrocarbons but has established the method so that it can provide support to the NRLs and OCLs if required.

Activity area 1d – Training

Training requests had been received from three NRLs (Romania, Hungary and Sweden). Representatives from the Swedish and Hungarian NRLs attended an EURL organised training course in November 2012. Romania declined to attend.

In addition the JRC conducted on behalf of the JRC Programme for enlargement and Integration a dedicated workshop in November 2012.

The two trainings were combined into one week (with workshop for E&I comprising also NRLs staff) and followed by the hands on training only for NRL staff.

Customer satisfaction surveys were conducted for both and showed full satisfaction.

Report:

Enlargement and Integration workshop: "EU legislation and testing for the chemical safety of food contact material". C. Simoneau, E. Hoekstra, N. Jakubowska EUR 25599, 2012 (JRC76765, 1831-9424, IBSN 978-92-79-27392-6, doi: 10.2788/67212)

² MOAH – mineral oil aromatic hydrocarbons

³ MOSH – mineral oil saturated hydrocarbons

Activity Area 1e- Technical support to disputes

No requests were received.

General tasks

Operational procedures

Compilation of reports and cost estimates

The EURL-FCM prepared and published reports associated with the above work (see section outputs).

The EURL submitted timely to the Commission a financial and technical report on the operation of the EURL-FCM for the Annual Report 2011 which was accepted with full satisfaction. It also submitted an intermediate 2012 report of the EURL-FCM (Period 01/01/2011-31/07/2012) by 1st September 2012, together with the work programme and associated budget on the operation of the laboratory for the work programme 2013.

It submitted timely to the Commission the financial and technical reports for each workshop of the EURL-FCM and conducted the relevant customer satisfaction surveys.

Documentation services, internal and external communication, interchange of information via the web site

The web portal http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m was maintained and updated. The platform supports the public dissemination of the work on food contact. The website holds information about the activities and events carried out by the EURL as well as published reports available and scientific papers. As a follow up of a previous feedback the Network pages were made more visible.

The dedicated website on Circa specifically for NRLs is designed to support dissemination of information and network activities. The platform represents a main source of information exchange between the EURLs and the NRLs as well as it is used for repository of working documents and traceability purposes. In May 2012, the Commission started a complete overhaul from the former Circa platform to the a new Circabc platform. The EURL-NRL platform was in the first batch moved. The transition was not easy as the new platform seems to be missing quite a lot of features that were more straightforward on the former platform (bulk uploads of documents, moving documents between folders while keeping the traceability of the original dates). In addition the system was particularly slow in the first months of operation so far. Forms and related documentation for NRLs to conduct ILCs were uploaded in specific locations as in the past.

CIRCABC – jrccrlfcm can be found at:

<https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal: idcl=FormPrincipal:left-menu-ig->

link&FormPrincipal_SUBMIT=1&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAE3cHQAKy9qc3AvZXh0ZW5zaW9uL3dhaS9uYXZpZ2F0aW9uL2NvbnRhaW5lci5qc3A=

Periodical updates for public website and continuous update throughout the year for Circa website were performed.

Ad-hoc questions or exchange of information with NRLs

The EURL-FCM conducted work to evaluate and respond to issues, in particular via the development and implementation of a functional mailbox. JRC-IHCP-EURL-FCM@jrc.ec.europa.eu

It supported by means of information and technical advice both via the functional mailbox, but also by direct help function by e-mail. It liaised with NRLs on a regular basis both via e-mail and via the Circa platform to ensure rapid flow of information.

The EURL maintained close awareness of developments in methodologies. It reported and advised, as relevant, to the annual plenaries and workshops of the National Reference Laboratories. This was also reported in the technical reports of the plenaries in order to provide brief for absentees.

Technical and scientific support to the Commission (EURL context)

The EURL attended the DG SANCO Working Party of Member State Competent Authorities (MS CA) meetings (4-5 per year) to brief on the progress and issues of the Network of NRLs as well as the achievements, milestones and performance of NRLs/OCs on ILCs. The 2012 ILCs showed a good performance of NRLs, and improved results compared to the previous round for the same test.

Quarterly statistics of MS CA on compliance check for melamine and polyamide under the regulation 284/2011 showed a decrease over the whole 2012 from 10% to 1% of non compliance for polyamide kitchen articles, while for melamine the non compliance showed also a decrease but less marked. This implied that the guidelines for testing compliance are well understood and have contributed to better control for compliance for export from China and Hong Kong and the improvement of the market situation in the EU. The guidelines in particular have eliminated previous discrepancies on test conditions and provide a solid basis for failing or passing compliance, which was exactly its purpose.

Organisation of plenary and workshops

The EURL organised the annual plenaries and workshops of NRLs.

The first plenary took place in June 2012. The agenda included the preparation of the work programme 2013, as well as discussion of results of the ILC 2011 formaldehyde and the drafting of the compilation of outputs and recommendation of the ILC Tenax. The workshop included a session on general exchange of information and information from the Commission.

The second plenary took place in December 2012. The programme included a review of the results of the ILC 2012 on formaldehyde and PAAs as well as the work programme as a whole. The workshop also included a session on general exchange of information and information from the Commission.

Quality assurance and control

The Quality System (QS) implemented since 2003 continued overseeing, controlling and reporting on the activities, ensuring they were executed timely and to the expected standards of excellence. It also made sure that the budget was properly allocated and spent according to the rules. The QS supervised meeting records and kept summaries of all documents ready for external audits. Continuous evaluation/improvement of the quality of the service deliveries were done and corrective actions were taken where the case. Evaluation sheets as feedback from NRLs and Official Laboratories were developed and implemented. Customer satisfaction surveys were conducted for the events of the EURLs, in particular the plenaries and the training for the evaluation of the work done, the meetings held or the progress and communications. They showed high level of satisfaction and were evaluated according to the QA process towards the traceability of key performance indicators for DG SANCO. The EURL-FCM received excellent feedback and evaluations from DG SANCO and NRLs for the timely and complete inputs and reports.

Other achievements

Conferences, publications

See outputs.

Outputs received international recognitions in peer review journals (3 peer-review publications), and Commission reports (4 EUR scientific and policy reports, 1 EUR training, 2 EUR scientific database and information systems, and 2 EUR Reference measurement).

The work on Tenax led to a permanent invitation to participate in CEN TC 172/WG3 (paper and board in contact with foods).

The EURL staff was invited as key speaker in 3 international events (one on nanopackaging, one on quality of methods, and one on food safety), invited as chair of session in International conferences (“Food Safety of Packaging” and “Food Factory for the future”) and at corporate level on-site (ca. 20 visitors or groups).

The JRC for FCM also served as scientific committee member to two major internal conferences (ILSI 2012 and Food Factory) and on the advisory board for one RTD project (SATIN). It was called on referring 4 peer-review articles for high ranking journals in the field.

Several items were presented on the work of the EURL at international conferences (In particular the validation of the method for Tenax and the overall 5 year review of ILCs)

FACET

The 7th Framework EU funded project Flavourings, Additives and Food Contact materials Exposure Tool, or in short FACET, was an EU project whose scope was to estimate exposure to flavours, additives and food contact materials across Europe. The JRC was involved a major partner on the generation of scientific and experimental data on food contact materials.

JRC contributed to a consortium of 20 collaborative partners across the EU, from industrial, academic and public body research centres. For the first time industry in conjunction with academia working in concert produced a unique multi-disciplinary evaluation tool to simultaneously estimate exposure assessment to food additives, flavourings and food contact materials. This novel tool was also unique in having developed and validated models underpinning the scientific output.

The FACET tool was finalised as a software tool containing interacting databases of chemical concentrations for flavourings and additives, chemical occurrence data, industry data on retail packaging composition, and food consumption diaries. These databases are combined in probabilistic dietary exposure models that estimate exposure in different populations of consumers in the EU. FACET provides for the first time a validated software programme for deterministic and probabilistic modelling of food chemical intake. The desktop software can be downloaded, installed, so that the assessments can be run on the user's computer.

JRC was also the organiser of the final conference. The project closing conference was held on 26th October in Brussels and the software generated from the project was demonstrated. The conference organised by JRC was very successful with more than 120 target stakeholders. Professional industrial associations, Member States authorities, EFSA, various services of the Commission including DG SANCO, DG ENTR and DG RTD had a number of representatives present to the event.

JRC developed the website and one stop portal for the access to novel tool.

The software will continue to be available under the stewardship of the JRC. JRC was established from the inception of the project as responsible for the implementation, acceptability, and sustainability of the final product (software) and for the future use of the tool by stakeholders. Training will be arranged first of all for EFSA and then for regulators including NRLs who wished so in 2013.

The JRC was also responsible for linking progress and new knowledge generated by the project to other EU project and initiatives, which it did in particular to update the EU database Expofacts.

This resulting food chemical exposure surveillance system, serves the needs of the EU regulatory authorities in the protection of consumer health, and will now be sustainable thanks to the continuous action from the JRC for its implementation and training in particular to Commission, EFSA and the industry value chain.

Report

Proceedings of the Final conference FP7 RTD project FACET (Flavours, Additives and food Contact materials Exposure Tool) 26th October 2012 Brussels, Belgium, Scientific information systems and databasesEUR 25538 EN, ISSN: 1831-9424, ISBN: 978-92-79-26846-5; doi:10.2788/52753

Outputs

Publications

Annual Report 2011 of the European Union Reference Laboratory for Food Contact Materials, SIMONEAU Catherine; JRC70056, 2012 Scientific and Policy Reports

Report of the interlaboratory comparison organised by the European Reference Laboratory for Food Contact Materials: ILC01 2012- Formaldehyde and Melamine in 3% acetic acid migration solution; BELDI Giorgia; JAKUBOWSKA Natalia; YAVUZ Oguzhan; SIMONEAU Catherine; JRC77619 Scientific and Policy Reports EUR 25686-EN ISSN: ISSN 1831-9424, ISBN: 978-92-79-28085-6, doi:10.2788/77358

Report of the 17th plenary workshop of the European Union Reference Laboratory for Food Contact Materials and its Network of National Reference Laboratories : 2012 mid-year progress review and establishment of work programme 2013; Dublin, 26-27 June 2012" SIMONEAU Catherine; JRC73184, JRC Technical Reports, EUR 25474 EN (2012), ISSN : 1831-9424, ISBN: 978-92-79-26059-9, doi:10.2788/44196

Report of the interlaboratory comparison organised by the European Reference Laboratory for Food Contact Materials: ILC02 2012- Primary Aromatic Amines in 3% acetic acid migration solution, BELDI Giorgia; JAKUBOWSKA Natalia; BRADLEY Emma; SIMONEAU Catherine; JRC77620 2012, Scientific and Policy Reports EUR 25685 (2012), ISSN :1831-9424, ISBN : 978-92-79-28084-9, doi:10.2788/77260

Development of a harmonised method for specific migration into the new simulant for dry foods established in Regulation 10/2011: Establishment of precision criteria from an EU interlaboratory comparison organized by the EURL- Food Contact Materials for the quantification from and migration into poly(2,6-diphenyl phenylene oxide)" BELDI Giorgia; JAKUBOWSKA Natalia; PEYCHES BACH Aurelie; SIMONEAU Catherine; JRC77515, Scientific and Policy Reports EUR 25680 EN (2012), ISSN: 1831-9424, ISBN: 978-92-79-28078-8, doi: 10.2788/76804.

Report of the interlaboratory comparison organised by the European Reference Laboratory for Food Contact Material - ILC01 2011- Formaldehyde in food contact migration solution, BELDI Giorgia; JAKUBOWSKA Natalia; DERDA Malgorzata; SIMONEAU Catherine; JRC68630 2.2.c Validated methods, Reference methods and measurements, EUR 25226 EN (2012); ISSN: 1831-9424, ISBN:978-92-79-23111-7; doi:10.2788/13916

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Enlargement and Integration workshop: "EU legislation and testing for the chemical safety of food contact material" Catherine; HOEKSTRA Eddo; JAKUBOWSKA Natalia; JRC76765, Training EUR 25599 EN (2012) ISSN: 1831-9424, ISBN: 978-92-79-27392-6; doi:10.2788/67212

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Identification and quantification of the migration of chemicals from plastic baby bottles used as substitutes for polycarbonate, SIMONEAU Catherine; VAN DEN EEDE Liza; VALZACCHI Sandro; JRC68595 Food Additives and Contaminants - Part A Chemistry, Analysis, Control, Exposure and Risk Assessment 29 (3) , pp. 469-480 (2012)

Release of bisphenol A from polycarbonate - a review, HOEKSTRA Eddo, SIMONEAU Catherine, Critical Reviews in Food Science And Nutrition, V53 N3, p.386-402, ISSN: 1040-8398, doi: 10.1080/10408398.2010.536919,

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Proceedings of the Final conference FP7 RTD project FACET (Flavours, Additives and food Contact materials Exposure Tool) 26th October 2012 Brussels, Belgium, Scientific information systems and databasesEUR 25538 EN, ISSN: 1831-9424, ISBN: 978-92-79-26846-5; doi:10.2788/52753

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Migration studies: Kinetic migration tests for 9 foodstuffs using 10 different model migrants and comparative tests using the food simulant Tenax®" BACH Aurelie; SIMONEAU Catherine; 2.3 JRC Technical Reports

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Interlaboratory comparison organized by the European Reference Laboratory for Food Contact Material in 2011 -2012: formaldehyde JRC72298 2012, Plenary EURL-FCM June 2012, 26-27 June 2012, Dublin (IE)

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Microbiological and Chemical Food Safety: from biofilms to food contact materials, SIMONEAU Catherine; JRC72325 2012 Food Factory for the Future, July 04-06, Laval (FR)

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Classification of foodstuffs based on their solubility properties for potential migrants from food contact materials in support of exposure estimation FRANZ Roland; DRIFFIELD Malcom; MERCEA Peter; PASEIRO-LOSADA P.; SIMONEAU Catherine; SEILER Annika; JRC75677 ILSI International Symposium on Food Packaging – Scientific Developments supporting Safety and Innovation, 14-16 November 2012, Berlin (DE)

A global evaluation of reliability of results of compliance of official controls across the EU for the safety of food contact materials via EU wide interlaboratory comparisons 2008-2012. SIMONEAU Catherine; BELDI Giorgia; JAKUBOWSKA

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Migration modelling for compliance testing of plastic food contact materials, HOEKSTRA Eddo, JRC76772, 2012, Enlargement and Integration workshop "EU legislation and testing for the chemical safety of food contact material", November 06-07 2012, Ispra (IT)

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European Commission

EUR 26187 – Joint Research Centre – Institute for Health and Consumer Protection

Title: Annual Activity Report 2012 - European Union Reference Laboratory for Food Contact Materials

Author(s): Catherine Simoneau

Luxembourg: Publications Office of the European Union

2013 – 25 pp. – 21.0 x 29.7 cm

EUR – Scientific and Technical Research series –ISSN 1831-9424 (online)

ISBN 978-92-79-33268-5 (pdf)

doi:10.2788/29363

Abstract

In 2012, three interlaboratory comparisons (ILC) were completed. The ILCs were 1) the evaluation of a method for migration into a dry material (Tenax) that officially simulates all dry foods, 2) determination of melamine and of formaldehyde in 3% acetic acid migration solutions, and 3) determination of primary aromatic amines in 3% acetic acid migration solutions. The work programme also included the collation by the EURL of food contact substances and methodology for their determination in plastics, food simulants or foodstuffs, work to establish methodology for mineral hydrocarbons, training activities carried out by the EURL and the preparation of technical guidelines in support of Regulation EU No. 10/2011.

As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

Working in close cooperation with policy Directorates-General, the JRC addresses key societal challenges while stimulating innovation through developing new standards, methods and tools, and sharing and transferring its know-how to the Member States and international community.

Key policy areas include: environment and climate change; energy and transport; agriculture and food security; health and consumer protection; information society and digital agenda; safety and security including nuclear; all supported through a cross-cutting and multi-disciplinary approach.